K032594

SEP - 5 2003

I. 510(k) SUMMARY

This summary is submitted in compliance with 21 CFR §807.92

Submitted by:	Scanditronix / Wellhofer Bahnhofstrasse 5 90592 Schwarzenbruck (Germany) Phone: +49-9128-607-0 FAX: +49-9128-607-10
Contact Person:	Martin Arold
Date Prepared:	February 1, 2003
Proprietary Name:	WP 1D
Common Name:	Clinical Reference Dosimetry Phantom
Classification Name:	Accelerator, linear, medical, §892.5050
Predicate Device:	Water Phantom MT-150 (MEDTEC Inc.) Motorized Depth Dose Apparatus (MEDTEC Inc.) K943199, 12/07/1994

(1) Description of the Device:

The Clinical Reference Dosimetry Phantom **WP 1D** comprises a one-dimensional precision servo-mechanism attached to a Perspex (PMMA) water tank. Various radiation detectors can be positioned along a vertical guide rail in different depths according to the application needs.

The "Manual Version" consists of the basic phantom, equipped with a self-locking hand crank to move the detector. That hand crank is coupled to a battery powered, reset-able position indicator that displays the depth.

The "SCU Version" consists of the basic phantom, equipped with a motor/potentiometer device to move the detector. An electronic servo control unit (SCU) consisting of a handheld Remote Control and a Motor Control unit is used to position the detector to a user definable or stored depth.

(2) Intended use:
The Clinical Reference Dosimetry Phantom **WP 1D** is used to position various radiation detectors in water or air. It consists of a cubic tank and a precision one-dimensional hand crank or motor driven servo. By design it is suitable to act as a phantom according to various dosimetric protocols (e.g. AAPM's TG-51 or IAEA's TRS-398). The device is intended to be used by experienced professionals entrusted with dosimetric functions only.

(3) Technological comparison:
The **WP 1D** is a clinical Reference Dosimetry System similar to the MEDTEC Inc. Depth Dose Apparatus, K943199, 12/07/1994.
Both devices consist of an acrylic water tank equipped with a one-dimensional scanning mechanic to position various radiation sensors in different water depths.
Both scan mechanics may be driven manually or motor controlled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Wellhöfer Dosimetrie
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K032594
Trade/Device Name: One Dimensional Water Phantom, Model WP-1D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: August 8, 2003
Received: August 22, 2003

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. INDICATIONS FOR USE STATEMENT

510(k) Number: (not known) K032594

Device Name: WP 1D

Indications For Use: The Clinical Reference Dosimetry Phantom WP 1D is used to position various radiation detectors in water or air. It consists of a cubic tank and a precision one-dimensional hand crank or motor driven servo. By design it is suitable to act as a phantom according to various dosimetric protocols (e.g. AAPM's TG-51 or IAEA's TRS-398). The device is intended to be used by experienced professionals entrusted with dosimetric functions only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR §801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032594